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TREXLER, BUSINELL, GIANGIORGIO, BLACKSTONE & MARR, LTD. 105 WEST ADAMS STREET SUITE 3600 CHICAGO, IL 60603			YOUNG, RACHEL T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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ptodocket@trexlaw.com

Office Action Summary	Application No. 10/575,324	Applicant(s) GRADON ET AL.
	Examiner RACHEL T. YOUNG	Art Unit 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 January 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36-54 and 56-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 36-54 and 56-79 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 January 2010 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Amendment

1. This office action is responsive to the preliminary amendment filed on 1/28/10. As directed by the amendment: claims 1-35 and 55 have been canceled, and new claims 70-79 have been added. Thus, claims 36-54 and 56-79 are presently pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 78-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 78, lines 1-4 recite "said one end", "said opposite side" and "said first end" and "said mask inlet", which all lack proper antecedent basis. Claim 79, line 4 recites "the mask", which lacks proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 36-37, 39-41, 43-45, 47-49, 53 and 56-63 are rejected under 35

U.S.C. 103(a) as being unpatentable over Hecker et al. (6,595,214) in view of Jestrabek-Hart (6,470,886).

As to claim 36, Hecker discloses a device for delivering a supply of gases (Fig. 2) to a user including an interface including a hollow body (1 and 2) (Fig. 2), a gases inlet (23) (Fig. 2) and a sealing member (1) (Fig. 2) to rest against the face of a user, adapted in use to supply gases to the user (Col. 4, ll. 29-31) (Fig. 2), a conduit (5) (Fig. 2) supplying the gases to the interface, the conduit attached to an inlet to the hollow body (Fig. 2), and headgear adapted to attach to the interface and around the head of the user (Col. 5, ll. 3-5), the conduit includes at least one angular adjustment mechanism (3) (Fig. 2) to allow for angular adjustment of the interface (Col. 3, ll. 14-27). Hecker is silent regarding a sling connected to the headgear to connect and support the conduit. However, in fig. 6C Jestrabek-Hart teaches a sling (27 and 32) connected to headgear that connects to and supports the conduit. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear and conduit with a sling to support the conduit, as taught by Jestrabek-Hart, for the purpose of providing support to the conduit and keeping it in one position.

As to claim 37, Hecker discloses that the angular adjustment means is at least one joint and the joint is a ball and socket joint (Col. 3, ll. 29-32).

As to claims 39 and 41, Hecker discloses that at least one angular adjustment means is a section of flexible conduit (3) (Fig. 2) (Col. 3, ll. 15-27), and that the conduit is supported in relation to the headgear such that any load on the conduit is taken by the headgear and not the interface (Fig. 2).

As to claim 40, the modified Hecker discloses that the flexible conduit includes a malleable band (13, Fig. 6C and 7D Jestrabek-Hart).

As to claims 43-45, Hecker discloses that the hollow body has a forehead rest ("forehead plate" 10) (Fig. 2, 3) with harnessing slots (10, 11) (Fig. 3) to secure the hollow body to the headgear, that the conduit includes a first conduit (5) (Fig. 2) connected to a second conduit (3) (Fig. 2) that attaches to the inlet of the interface (Fig. 2), and that the second conduit is more flexible than the first conduit (Col. 3, ll. 14-27).

As to claims 47-49, Hecker discloses that the conduit is attached to the headgear by fastening means ("latching clip" 15) (Fig. 2), that the headgear includes a transverse strap (Fig. 3) (Col. 5, ll. 3-5) which in use lies on top of the user's head, and that the transverse strap includes a fastening means (12) (Fig. 3) (Col. 5, ll. 3-5).

As to claim 53, Hecker discloses that the headgear includes a plurality of straps (Col. 5, ll. 3-5) including at least one side strap (Col. 5, ll. 3-5) that the conduit is attached to by the fastening means (12) (Fig. 3) (Col. 5, ll. 3-5).

As to claims 56-57, the modified Hecker's mask discloses a sliding strap (Jestrabek-Hart 32, 27, Fig. 6C) that attaches to the conduit to provide support to the conduit, and that the device includes an additional strap attachment (Jestrabek-Hart 32, 27, Fig. 6C) between the headgear and the conduit to restrain the conduit from moving.

As to claims 58-59, Hecker discloses that the headgear includes adjustment means ("forehead-plate mount" 9) (Fig. 2, 3) to adjust the vertical distance between the headgear and the interface (Col. 2, ll. 12-17), and that the adjustment means is substantially tubular housing that restrains the conduit yet allows the conduit to move through it (Fig. 2-3) (Col. 2, ll. 12-17).

As to claims 60-61, Hecker discloses that the conduit includes a plurality of detents (Fig. 2) and a housing (9) (Fig. 3) includes a protrusion (Fig. 3) that interacts with the detents when the conduit is moved to adjust the vertical distance between the headgear and the interface (Col. 2, ll. 12-17) (Col. 5, ll. 6-45), and that the headgear includes a transverse strap (Col. 5, ll. 3-5) including a support portion ("collar" 24 and "forehead plate" 10) (Fig. 3) capable of receiving the conduit to support and decouple movement of the conduit from the interface (Fig. 2).

As to claim 62, Hecker teaches that the support portion is curved in shape (Fig. 3), however is silent regarding that it has an upper arm and lower arm, the upper arm being more flexible than the lower arm, each of the arms receive the conduit and support the conduit above the headgear. However, Jestrabeck-Hart teaches that it has an upper arm (Fig. 6C) and lower arm (Fig. 6C), and that each of the arms receive the conduit (Fig. 6C) and support the conduit above the headgear (Fig. 6C). Although Jestrabeck-Hart lacks details regarding that the upper arm is more flexible than the lower arm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hecker's headgear such that the upper arm is more flexible than the lower arm since it has been held that discovering an optimum

value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). It also would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include an upper arm and lower arm, and each of the arms receive the conduit and support the conduit above the headgear, as taught by Jestrabek-Hart, for the purpose of providing more structural support to the respiratory conduit.

As to claim 63, Hecker discloses that the support portion ("collar" 24 and "forehead plate" 10) (Fig. 3) is an elongate member capable of restraining the conduit (Fig. 2, 3).

6. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Jestrabek-Hart as applied to claim 36 above in view of Demers et al. (20020056457 A1).

As to claim 38, Hecker discloses that at least one joint is two ball and socket joints (Col. 3, ll. 29-32), however is silent regarding them having rectangular profiles to limit pivoting of each of the joints through one axis. However, Demers teaches them having rectangular profiles to limit pivoting of each of the joints through one axis (Fig. 7a). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's ball and socket joints with rectangular profiles to limit pivoting of each of the joints through one axis, as taught by Demers, for the purpose of providing a more controlled angular adjustment needed for better comfort for a user.

7. Claims 42, 46, 50, 54, 64 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Jestrabek-Hart as applied to claim 36 above in view of Ging et al. (20030196662 A1)

As to claims 42 and 46, the modified Hecker is silent regarding that there is a sliding connection between the headgear and the interface when the interface is engaged with the user, and that the headgear has a plurality of hook and loop attachments that enable connection of the headgear to the interface. However, Ging teaches that there is a sliding connection ("connector element" 128) (Fig. 1) between the headgear and the interface when the interface is engaged with the user, and that the headgear has a plurality of hook and loop attachments (Page 6, ¶ 120, II. 10-11) that enable connection of the headgear to the interface. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include that there is a sliding connection between the headgear and the interface when the interface is engaged with the user, and that the headgear has a plurality of hook and loop attachments that enable connection of the headgear to the interface, as taught by Ging, for the purpose of providing structural support tightening or loosing means for the comfort of the user.

As to claims 50 and 54, the modified Hecker's device of claims 42 and 46 discloses that the fastening means is a hook and loop attachment (Ging Page 6, ¶ 120, II. 10-11) and that the headgear attaches to the interface by a sliding strap (Ging 96, Fig. 1).

As to claim 64, Hecker discloses that the headgear is comprised of a forward substantially rigid part (9) (Fig. 3) (Col. 5, ll. 64-65), however is silent regarding a backward soft part. Ging teaches a backward soft part (84) (Fig. 1) (Page 6, ¶ 120, ll. 39-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear to include a backward soft part, as taught by Ging, for the purpose of providing comfort to the user.

As to claim 67, the modified Hecker is silent regarding that the backward soft part is formed of a stretchable, breathable material. However, Ging teaches that the backward soft part is formed of a stretchable, breathable material (Page 6, ¶ 120, ll. 7-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hecker's headgear to include that the backward soft part is formed of a stretchable, breathable material, as taught by Ging, for the purpose of providing structural support tightening or loosing means for the comfort of the user.

As to claim 68, Hecker is silent regarding that headgear includes tightening means that allows the adjustment of a backward soft part. However, Ging teaches that headgear includes tightening means (150) (Fig. 1) that allows the adjustment of a backward soft part (84) (Fig. 1) (Page 6, ¶ 120, ll. 39-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear such that the headgear includes tightening means that allows the adjustment of a backward soft part, as taught by Ging, for the purpose of providing structural support tightening or loosing means for the comfort of the user.

8. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Jestrabeck-Hart as applied to claim 48 above in view of McDonald et al. (2001/0042547 A1).

As to claim 51, Hecker discloses that a transverse strap is connected to a forehead rest (Fig. 3), however is silent regarding by a telescopic extension mechanism. However, McDonald teaches a telescopic extension mechanism (Page 2, ¶ 27) (Fig. 5). Although the telescopic mechanism is not used in conjunction with a forehead rest, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hecker's headgear such that a transverse strap is connected to a forehead rest by a telescopic extension mechanism, as taught by McDonald, for the purpose of providing a proper location for the forehead rest.

9. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Jestrabek-Hart as applied to claim 48 above in view of Berthon-Jones et al. (2006/0118119).

As to claim 52, Hecker is silent regarding that the transverse strap is connected to a forehead rest by an adjustable glider mechanism and that the glider mechanism allows a sliding connection between the headgear and the forehead rest, however Berthon-Jones teaches that a transverse strap (624, Fig. 15) is connected to a forehead rest (800, Fig. 15) by an adjustable glider mechanism (634, Fig. 15) and that the glider mechanism allows a sliding connection between the headgear and the forehead rest (Page 6, para 78, ll. 17-20). Therefore, it would have been obvious to one of ordinary

skill in the art at the time the invention was made to modify the modified Hecker's transverse strap to include a sliding glider mechanism between the transverse strap and the forehead rest, as taught by Berthon-Jones, for the purpose of providing adjustment for the user to enhance comfort.

10. Claims 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Jestrabek-Hart/Ging as applied to claim 64 above in view of Sprinkle (7,290,546).

As to claims 65-66, Hecker's modified device discloses that the forward substantially rigid part includes a substantially rigid layer (9) (Fig. 3) (Hecker Col. 5, II. 64-65). Hecker is silent regarding, and a padding layer that is removable from the rigid layer. However, Sprinkle teaches a padding layer (52) (Fig. 1) that is removable (Col. 4, II. 16-26) from the rigid layer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hecker's mask to include a padding layer that is removable from a rigid layer, as taught by Sprinkle, for the purpose of providing comfort to the user and ease of manufacturing.

11. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hecker/Jestrabek-Hart/Ging as applied to claim 68 above in view of Bordewick et al. (2004/0035427 A1).

As to claim 69, Hecker's modified device discloses the tightening means (Ging 150) (Fig. 1) where a length of elastic (Ging 96) (Fig. 1) (Page 2, ¶ 23, II. 12) is attached

to a forward substantially rigid part (9) (Fig. 3) (Hecker Col. 5, ll. 64-65) but extends over a backward soft part (Ging 84) (Fig. 1) (Page 6, ¶ 120, ll. 39-41). The modified Hecker's mask is silent regarding a toggle which the length of elastic is capable in use of being pulled through to tighten the backward soft part in relation to a forward substantially rigid part. However, Bordewick teaches a toggle ("quick-sizing cord" 7) (Fig. 1) which the length of elastic is capable in use of being pulled through to tighten the backward soft part in relation to the forward substantially rigid part (Page 2, ¶ 23, ll. 27-29) (Page 2, ¶ 17, ll. 1-4).

12. Claims 70-74 and 76-79 rejected under 35 U.S.C. 103(a) as being unpatentable over Ging in view of Jestrabek-Hart.

Regarding claim 70, in fig. 1 Ging discloses an interface 40 including a hollow body (40, fig. 6b), a gases inlet 25 and a sealing member (40, Page 12, para 171) that rests against the face of a user in use, that supplies gases to the user (Page 3, para 27), a conduit 310 supplying the gases to the interface, the conduit attached to an inlet to the hollow body, a headgear (140, 88, 138, 96) attached to the interface and around the head of the user. Ging is silent regarding a support strap attached to the headgear that forms a loop to connect to and support the conduit. However, Jestrabek-Hart teaches a support strap (Fig. 11A) attached to the headgear, the support strap forming a loop to connect to and support the conduit (Fig. 11A). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ging's headgear with a support straps attached to the headgear that forms a loop to

connect and support the conduit, as taught by Jestrabek-Hart, for the purpose of providing added support to the conduit.

Regarding claim 71, the modified Ging discloses that the support strap connects to the conduit below the mask inlet as the conduit hangs vertically below the mask inlet as described in the rejection of claim 70.

Regarding claim 72, the modified Ging discloses that the support strap is a sling connecting to the headgear and the conduit as described in claim 70 above.

Regarding claim 73, the modified Ging discloses that the support strap is a sliding strap that connects to the headgear and the conduit, allowing a sliding connection between the headgear and the conduit and the loading on the tubing is transferred to the headgear. Jestrabek-Hart's support strap can allow a slight amount of sliding of the conduit and also takes some load off of the mask providing support to the mask.

Regarding claim 74, in fig. 1 Ging discloses that there is a sliding connection 128 between the headgear 140 and the interface when the interface is engaged with the user.

Regarding claim 76, the modified Ging of claim 73 discloses that the headgear attaches to the interface by a sliding strap.

Regarding claim 77, Ging discloses that the headgear includes a transverse strap 96, and the modified Ging discloses that the support strap connected to the transverse strap and extending below the mask inlet as described in the rejection of claim 70.

Regarding claim 78, the modified Ging of claim 70 discloses that one end of the support strap connects to one side of the headgear, a second of the support strap connecting to an opposite side of the headgear as the first end of the support strap, the strap extending below the mask inlet, the strap arranged to form a loop and connect to the conduit below the mask inlet.

Regarding claim 79, the modified Ging discloses and interface, a support strap that transfers load on the mask to the headgear that is slides relative to the mask mask to reduce forces on the mask due to downward drag from the conduit, but is silent regarding that the interface includes at least one engaging clip, the top part of the support strap including a mid-section intended to reciprocate with the engaging clip. However, Jestrabek-Hart teaches an engaging clip 23 and the top part of the support strap including a mid-section intended to reciprocate with the engaging clip in fig. 16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Ging's interface with an engaging clip that allows the support strap to reciprocate with it, as taught by Jestrabek-Hart, for the purpose of providing better support to the mask.

13. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ging/Jestrabek-Hart as applied to claim 70 above in view of Berthon-Jones (2006/0118119).

Regarding claim 75, the modified Ging discloses headgear and a transverse strap 84, but is silent regarding that the transverse headgear strap is connected to a

forehead rest by an adjustable glider mechanism. However Berthon-Jones teaches that a transverse strap (624, Fig. 15) is connected to a forehead rest (800, Fig. 15) by an adjustable glider mechanism (634, Fig. 15) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Hecker's transverse strap to include a sliding glider mechanism between the transverse strap and the forehead rest, as taught by Berthon-Jones, for the purpose of providing adjustment for the user to enhance comfort.

Response to Arguments

14. Applicant's arguments filed 1/28/10 have been fully considered but they are not persuasive. Applicant argues on pages 16-17 that Jestrabek-Hart does not disclose a sling referencing a definition from *Merriam and Webster Dictionary* that a sling is "usually a looped line used to suspend or carry something" on the bottom of page 16. In fig. 6C Jestrabek-Hart clearly shows a sling (27 and 32) used to suspend a conduit and keep it substantially steady in the form of a loop with the headgear to add support. On page 17, II. 15-16 applicant argues that Jestrabek-Hart's sling does not support the conduit, where in fact it clearly does in fig. 6C. On page 18, last para, applicant argues that Ging does not disclose a sliding connection between the headgear and the interface when the interface is engaged with the user. However, in fig. 1 Ging discloses connection 128 which indeed slides between headgear 140 and the interface 40, when in use. On page 19, 2nd para, applicant argues that Ging does not disclose that the headgear attached to the interface by a sliding strap. However, in fig. 1 Ging discloses

headgear 140 attached to interface 40 by sliding strap 96 (which slides through connector 128 in order to adjust the length of the strap). The arguments regarding claims 56 and 52 are moot in view of new grounds of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kwok et al. (6,044,844), Michel et al. (4,934,361) and Fecteau et al. (2002/0078953) to facemasks with headgear.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/
Examiner, Art Unit 3771

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772